



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,489	11/14/2003	Hau H. Duong	067456-5012-US02	1026
67374 7590 08/20/2008 MORGAN, LEWIS & BOCKIUS, LLP ONE MARKET SPEAR STREET TOWER SAN FRANCISCO, CA 94105				
EXAMINER				
LU, FRANK WEI MIN				
ART UNIT		PAPER NUMBER		
1634				
MAIL DATE		DELIVERY MODE		
08/20/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/714,489

Applicant(s)

DUONG ET AL.

Examiner

FRANK W. LU

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-25 is/are pending in the application.
4a) Of the above claim(s) 14-16 and 19 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 11-13, 17, 18 and 20-25 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on April 29, 2008 has been entered. The claims pending in this application are claims 11-25 wherein claims 14-16 and 19 have been withdrawn due to species election requirement mailed on May 27, 2007. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment filed on April 29, 2008. Claims 11-13, 17-18, and 20-25 will be examined.

Specification

2. The amendment filed on April 29, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: since page 33, second paragraph of the specification in original filed application only describes US applications 09/135,183 and 09/295,691, which has been abandoned and issued as US Patent No. 6,942,771 respectively, and this instant application was filed on November 14, 2003 (before September 21, 2004), US Patent No. 7,090,804 (US application 09/238,351) is incorporated by the reference (see page 3 of the amendment) is a new matter. See MPEP 608.04 (b).

Applicant is required to cancel the new matter in the reply to this Office Action.

Sequencing Listing

3. The sequencing listing filed on April 29, 2008 has been accepted by the office.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. New Matter

Claims 11-13, 17-18, and 20-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation “the input waveform eliciting a response of characteristic waveform that is unique to target analyte signals from the electrode indicative of electron transfer between the electron transfer moiety and the electrode” is added to the newly amended independent claim 11 while the recitation “receiving an output waveform that is unique to target analyte signals from the electrode, responsive to the input waveform” is added to the newly amended independent claim 25. Although page 103, first and second paragraphs of the specification suggested by applicant describe that “[B]ut, when correlated together, the data_{final} can have a characteristic response that is unique to target analysis signals” and “[A] characteristic curve of the peak information means a positive”, the specification fails to define or provide any disclosure to support such claim recitations in claims 11 and 29 because page 103, first and second paragraphs of the specification do not describe that a characteristic response that is unique to target analysis signals is waveform and the input waveform eliciting a response of characteristic waveform that

Art Unit: 1634

is unique to target analyte signals from the electrode is indicative of electron transfer between the electron transfer moiety and the electrode as recited in claims 11 and 29.

MPEP 2163.06 notes "If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11-13, 17-18, and 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 11 is rejected as vague and indefinite. Since providing and applying steps in the claim do not mention target analyte signals from the electrode, it is unclear what is characteristic waveform that is unique to target analyte signals from the electrode. Please clarify.

9. Claim 11 is rejected as vague and indefinite. Since the claim does not indicate how the characteristic waveform that is unique to target analyte signals is correlated with electron transfer between the electron transfer moiety and the electrode, it is unclear why the input waveform eliciting a response of characteristic waveform that is unique to target analyte signals from the

electrode can be indicative of electron transfer between the electron transfer moiety and the electrode. Please clarify.

10. Claim 25 is rejected as vague and indefinite. Since providing and applying steps in the claim do not mention target analyte signals from the electrode, it is unclear what is an output waveform that is unique to target analyte signals from the electrode. Please clarify.

11. Claim 25 is rejected as vague and indefinite. Since claim does not indicate how an output waveform that is unique to target analyte signals from the electrode is correlated with electron transfer between the electron transfer moiety and the electrode, it is unclear why analyzing the output waveform using chronocoulometry can identify electron transfer between the electron transfer moiety and the electrode and why the electron transfer between the electron transfer moiety and the electrode can be an indication of the presence of said analytes in the assay complex. Please clarify.

Response to Arguments

12. Applicant's arguments with respect to claims 11-13, 17-18, and 20-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

/Frank W Lu /, Primary Examiner, Art Unit 1634
August 14, 2008

Application Number**Application/Control No.**

10/714,489

Examiner

FRANK W. LU

**Applicant(s)/Patent under
Reexamination**

DUONG ET AL.

Art Unit

1634